

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure  
Serial No.: 10/037,435  
Confirmation No.: 4823  
Filed: 31 December 2001  
For: HYDROGEN PEROXIDE AND PERACETIC ACID INDICATORS AND METHODS

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### Amendments to the Claims

This listing of claims replaces all prior versions, and listings, of claims in the above-identified application:

1. (Currently Amended) A sterilization indicator comprising a substrate and an indicator composition disposed thereon, wherein the indicator composition comprises:
  - at least one salt ~~[[of]]~~ comprising a transition metal and an inorganic anion;
  - at least one colorant that changes color when exposed to hydrogen peroxide ~~and/or~~  
~~peracetic acid;~~ and
  - at least one binder resin;wherein the at least one salt of a transition metal and the at least one colorant are selected to indicate the presence of hydrogen peroxide ~~and/or peracetic acid;~~ and  
wherein the at least one salt of a transition metal is not the at least one colorant that changes color when exposed to hydrogen peroxide ~~and/or peracetic acid.~~
2. (Original) The sterilization indicator of claim 1, wherein the transition metal is selected from the group consisting of Group VIB, Group VIII, and Group IB transition metals, and combinations thereof.
3. (Cancelled)
4. (Previously Presented) The sterilization indicator of claim 1, wherein the colorant is selected from the group of classes of colorants consisting of Methane, Monoazo, Diazo, Triazo, Diazine, Thiazine, Xanthene, Oxazine, Cyanine, Anthraquinone, Benzodifuranone, Styryl, Phthalocyanine, Quinophthalone, Nitro, and Nitroso colorants, and combinations thereof, and/or

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a colorant selected from the group consisting of Victoria green S extra, Basic blue 41, Basic red 15, Acid green AX986, and Basic red 14 colorants, and combinations thereof.

5. (Original) The sterilization indicator of claim 1, wherein the indicator composition further comprises at least one colorant that does not change color when exposed to hydrogen peroxide.

6. (Currently Amended) A hydrogen peroxide indicator comprising a substrate and an indicator composition disposed thereon, wherein the indicator composition comprises:

at least one salt ~~[[of]]~~ comprising a transition metal and an inorganic anion;

at least one colorant selected from the group of classes of colorants consisting of Methane, Monoazo, Diazo, Triazo, Diazine, Thiazine, Xanthene, Oxazine, and Anthraquinone colorants, and combinations thereof, and/or a colorant selected from the group consisting of Victoria green S extra, Basic blue 41, Basic red 15, Acid green AX986, and Basic red 14 colorants, and combinations thereof; and

at least one binder resin;

wherein the at least one salt of a transition metal and the at least one colorant are selected to indicate the presence of hydrogen peroxide; and

wherein the at least one salt of a transition metal is not the at least one colorant.

7. (Original) The hydrogen peroxide indicator of claim 6, wherein the indicator composition further comprises at least one colorant that does not change color when exposed to hydrogen peroxide vapor.

8. (Original) The hydrogen peroxide indicator of claim 6, wherein the salt of a transition metal is selected from the group consisting of a copper salt, a cobalt salt, an iron salt, a chromium salt, and combinations thereof.

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9. (Original) The hydrogen peroxide indicator of claim 8, wherein the indicator comprises at least one iron salt.

10. (Previously Presented) The hydrogen peroxide indicator of claim 9, wherein the colorant is selected from the group consisting of Patent blue violet, Alkali blue 4B, Victoria pure blue BO, Acid fuchsin sodium salt, Alphazurine A, Methyl violet 2B, Ethyl violet, FD/C blue 1, Brilliant blue R, Lissamine green B, Erioglaucine, Eriochrome black T, Eriochrome blue black B, Cibacron brilliant red 3B, Chromotrope 2B, Amaranth, D&C red No. 33, Bordeaux R, Acid violet 7, Acid violet 5, Plasmocorinth B, Acid blue 113, Acid red 151, Acid black 24, Acid red 97, Direct red 75, Brilliant crocein MOO, Ponceau SS, Reactive black 5, Arsenazo 111, Direct blue 71, Azocarmine G, Methylene violet 3RAX, Toluidine blue O, Methylene green, Sulforhodamine B, Rhodanine 6G, Violamine R, Nile blue A, Basic blue 3, Brilliant cresyl blue BB, Basic red 15, Alizarin violet 3R, Victoria green S extra, Basic blue 41, Acid green AX986, Basic red 14, D&C green No. 5, and combinations thereof.

11. (Previously Presented) The hydrogen peroxide indicator of claim 10, wherein the colorant is selected from the group consisting of Victoria pure blue BO, Acid fuchsin sodium salt, Alphazurine A, Methyl violet 2B, Ethyl violet, FD/C blue 1, Brilliant blue R, Lissamine green B, Erioglaucine, Eriochrome black T, Eriochrome blue black B, Cibacron brilliant red 3B, Chromotrope 2B, D&C red No. 33, Acid violet 7, Acid violet 5, Plasmocorinth B, Acid blue 113, Acid red 151, Acid black 24, Acid red 97, Direct red 75, Brilliant crocein MOO, Ponceau SS, Reactive black 5, Arsenazo 111, Azocarmine G, Methylene violet 3RAX, Toluidine blue O, Methylene green, Sulforhodamine B, Rhodanine 6G, Violamine R, Nile blue A, Basic blue 3, Brilliant cresyl blue BB, Basic red 15, Alizarin violet 3R, Victoria green S extra, Basic blue 41, Acid green AX986, Basic red 14, D&C green No. 5, and combinations thereof.

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12. (Currently Amended) A hydrogen peroxide indicator comprising a substrate and an indicator composition disposed thereon, wherein the indicator composition comprises:

at least one salt ~~[[of]] comprising an inorganic anion and~~ cobalt, copper, chromium,  
~~[[and]] or combinations thereof;~~

at least one colorant that changes color when exposed to hydrogen peroxide vapor; and  
at least one binder resin;

wherein the at least one salt of cobalt, copper, chromium, ~~[[and]] or combinations thereof,~~  
and the at least one colorant are selected to indicate the presence of hydrogen peroxide; and

wherein the at least one salt of cobalt, copper, chromium, ~~[[and]] or combinations thereof,~~  
is not the at least one colorant that changes color when exposed to hydrogen peroxide vapor.

13. (Currently Amended) ~~[[The]] A hydrogen peroxide indicator of claim 12, wherein the~~  
comprising a substrate and an indicator composition disposed thereon, wherein the indicator  
composition comprises:

at least one salt [[is]] selected from the group consisting of cobalt chloride, cobalt acetate,  
cupric chloride, cupric sulfate, cupric acetate, chromium potassium sulfate, and combinations  
thereof;

at least one colorant that changes color when exposed to hydrogen peroxide vapor; and  
at least one binder resin;

wherein the at least one salt of cobalt, copper, chromium, or combinations thereof, and  
the at least one colorant are selected to indicate the presence of hydrogen peroxide; and

wherein the at least one salt of cobalt, copper, chromium, or combinations thereof, is not  
the at least one colorant that changes color when exposed to hydrogen peroxide vapor.

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14. (Previously Presented) The hydrogen peroxide indicator of claim 12, wherein the colorant is selected from the group of classes of colorants consisting of Methane, Monoazo, Diazo, Triazo, Diazine, Thiazine, Cyanine, Xanthene, Oxazine, and Anthraquinone colorants, and combinations thereof, and/or a colorant selected from the group consisting of Victoria green S extra, Basic blue 41, Basic red 15, Acid green AX986, and Basic red 14 colorants, and combinations thereof.

15. (Original) The hydrogen peroxide indicator of claim 12, wherein the indicator composition further comprises at least one colorant that does not change color when exposed to hydrogen peroxide vapor.

16. (Original) The hydrogen peroxide indicator of claim 12, wherein the indicator composition comprises at least one cobalt salt.

17. (Original) The hydrogen peroxide indicator of claim 16, wherein the colorant is selected from the group of classes of colorants consisting of Methane, Monoazo, Diazo, Oxazine, and Anthraquinone colorants, and combinations thereof.

18. (Original) The hydrogen peroxide indicator of claim 16, wherein the colorant is selected from the group consisting of Patent blue violet, Aniline blue, Erioglaucine, Arsenazo 1, Acid blue 92, Eriochrome blue black B, Congo red, Acid blue 29, Nile blue A, Reactive blue 2, Basic red 15, D&C green No. 5, and combinations thereof.

19. (Original) The hydrogen peroxide indicator of claim 12, wherein the indicator comprises at least one copper salt.

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20. (Previously Presented) The hydrogen peroxide indicator of claim 19, wherein the colorant is selected from the group of classes of colorants consisting of Methane, Monoazo, Diazo, Triazo, Diazine, Thiazine, Xanthene, Oxazine, Cyanine, and Anthraquinone colorants, and combinations thereof, and/or a colorant selected from the group consisting of Victoria green S extra, Basic blue 41, Basic red 15, Acid green AX986, and Basic red 14 colorants, and combinations thereof.

21. (Previously Presented) The hydrogen peroxide indicator of claim 20, wherein the colorant is selected from the group consisting of Alphazurine A, Methyl violet 2B, Ethyl violet, FD/C blue 1, Brilliant blue R, Lissamine green B, Erioglaucine, Victoria pure blue BO, Acid fuchsin sodium salt, Patent blue violet, Guinea green B, Coomassie violet R 150, Mordant brown 48, Chromotrope 2B, D&C red No. 33, Bordeaux R, Acid violet 7, Acid violet 5, Plasmocorinth, Acid red 151, Acid blue 29, Acid black 24, Acid red 97, Direct red 75, Brilliant crocein MOO, Ponceau SS, Reactive black 5, Arsenazo 111, Direct blue 71, Azocarmine G, Methylene violet 3RAX, Toluidine blue O, Azure B, Methylene green, Sulforhodamine B, Rhodanine 6G, Violamine R, Nile blue A, Basic blue 3, Brilliant cresyl blue BB, Quinaldine red, Basic red 15, Alizarin violet 3R, Reactive blue 2, Victoria green S extra, Basic blue 41, Acid green AX986, Basic red 14, D&C green No. 5, Fast green FCF, and combinations thereof.

22. (Previously Presented) The hydrogen peroxide indicator of claim 20, wherein the colorant is selected from the group of classes of colorants consisting of Methane, Monoazo, Diazo, Diazine, Thiazine, Xanthene, Oxazine, and Cyanine colorants, and combinations thereof, and/or a colorant selected from the group consisting of Victoria green S extra, Basic blue 41, Basic red 15, Acid green AX986, and Basic red 14 colorants, and combinations thereof.

23. (Previously Presented) The hydrogen peroxide indicator of claim 22, wherein the colorant is selected from the group consisting of Alphazurine A, Methyl violet 2B, Ethyl violet, FD/C blue

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1, Brilliant blue R, Lissamine green B, Erioglaucine, Victoria pure blue BO, Acid fuchsin sodium salt, Coomassie violet R 150, Mordant brown 48, Acid violet 5, Plasmocorinth, Acid red 151, Acid blue 29, Acid black 24, Acid red 97, Direct red 75, Arsenazo 111, Azocarmine G, Methylene violet 3RAX, Toluidine blue O, Methylene green, Rhodanine 6G, Basic blue 3, Brilliant cresyl blue BB, Quinaldine red, Basic red 15, Reactive blue 2, Victoria green S extra, Basic blue 41, Basic red 14, D&C green No. 5, and combinations thereof.

24. (Original) The hydrogen peroxide indicator of claim 12, wherein the indicator comprises at least one chromium salt.

25. (Original) The hydrogen peroxide indicator of claim 24, wherein the colorant is selected from the group of classes of colorants consisting of Methane, Monoazo, Diazo, and Cyanine colorants, and combinations thereof.

26. (Original) The hydrogen peroxide indicator of claim 25, wherein the colorant is selected from the group consisting of Ethyl violet, Eriochrome black T, Eriochrome blue black B, Congo red, Acid blue 113, Quinaldine red, and combinations thereof.

27. (Original) The hydrogen peroxide indicator of claim 26, wherein the colorant is selected from the group consisting of Ethyl violet, Eriochrome black T, Eriochrome blue black B, Acid blue 113, Quinaldine red, and combinations thereof.

28. - 37. (Cancelled)

38. (Currently Amended) A method of monitoring a sterilization process, the method comprising:  
providing an indicator comprising a substrate and an indicator composition comprising:

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at least one salt [[of]] comprising a transition metal and an inorganic anion;  
at least one colorant that changes color when exposed to a sterilant; and  
at least one binder resin;  
providing an article to be sterilized; and  
exposing the indicator and the article to be sterilized to a sterilant;  
wherein the at least one salt of a transition metal is not the at least one colorant that  
changes color when exposed to a sterilant.

39. (Currently Amended) A method of monitoring a hydrogen peroxide sterilization process, the  
method comprising:

providing a hydrogen peroxide indicator comprising a substrate and an indicator  
composition comprising:

at least one salt [[of]] comprising a transition metal and an inorganic anion;  
at least one colorant selected from the group of classes of colorants consisting of  
Methane, Monoazo, Diazo, Triazo, Diazine, Thiazine, Cyanine, Xanthene, Oxazine,  
Anthraquinone, Benzodifuranone, Styryl, Phthalocyanine, Quinophthalone, Nitro, and Nitroso  
colorants, and combinations thereof, and/or a colorant selected from the group consisting of  
Victoria green S extra, Basic blue 41, Basic red 15, Acid green AX986, and Basic red 14  
colorants, and combinations thereof; and  
at least one binder resin;  
providing an article to be sterilized; and  
exposing the hydrogen peroxide indicator and the article to be sterilized to hydrogen  
peroxide vapor;  
wherein the at least one salt of a transition metal is not the at least one colorant.



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40. (Currently Amended) ~~[[The]]~~ A method of claim 39, wherein the of monitoring a hydrogen peroxide sterilization process, the method comprising:

providing a hydrogen peroxide indicator, comprising a substrate and an indicator composition comprising:

at least one salt of a transition metal [[is]] selected from the group consisting of cupric chloride, ferrous chloride, cobalt chloride, cobalt acetate, cupric sulfate, ferrous sulfate, chromium potassium sulfate, cupric acetate, and combinations thereof;

at least one colorant selected from the group of classes of colorants consisting of Methane, Monoazo, Diazo, Triazo, Diazine, Thiazine, Cyanine, Xanthene, Oxazine, Anthraquinone, Benzodifuranone, Styryl, Phthalocyanine, Quinophthalone, Nitro, and Nitroso colorants, and combinations thereof, and/or a colorant selected from the group consisting of Victoria green S extra, Basic blue 41, Basic red 15, Acid green AX986, and Basic red 14 colorants, and combinations thereof; and

at least one binder resin;

providing an article to be sterilized; and

exposing the hydrogen peroxide indicator and the article to be sterilized to hydrogen peroxide vapor;

wherein the at least one salt of a transition metal is not the at least one colorant.

41. (Original) The method of claim 39, wherein the indicator composition further comprises at least one colorant that does not change color when exposed to hydrogen peroxide vapor.

42. (Currently Amended) A method of monitoring a hydrogen peroxide sterilization process, the method comprising:

providing a hydrogen peroxide indicator comprising a substrate and an indicator composition comprising:

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at least one salt [[of]] comprising an inorganic anion and copper, chromium, iron, cobalt, [[and]] or combinations thereof;

at least one colorant that changes color when exposed to hydrogen peroxide vapor;  
and

at least one binder resin;  
providing an article to be sterilized; and  
exposing the hydrogen peroxide indicator and the article to be sterilized to hydrogen peroxide vapor;

wherein the at least one salt of copper, chromium, iron, cobalt, [[and]] or combinations thereof, is not the at least one colorant that changes color when exposed to hydrogen peroxide vapor.

43. (Previously Presented) The method of claim 42, wherein the colorant is selected from the group of classes of colorants consisting of Methane, Monoazo, Diazo, Triazo, Diazine, Thiazine, Cyanine, Xanthene, Oxazine, Anthraquinone colorants, and combinations thereof, and/or a colorant selected from the group consisting of Victoria green S extra, Basic blue 41, Basic red 15, Acid green AX986, and Basic red 14 colorants, and combinations thereof.

44. (Original) The method of claim 42, wherein the indicator composition comprises at least one cobalt salt.

45. (Original) The method of claim 44, wherein the colorant is selected from the group of classes of colorants consisting of Methane, Monoazo, Diazo, Oxazine, and Anthraquinone colorants, and combinations thereof.

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46. (Original) The method of claim 44, wherein the colorant is selected from the group consisting of Patent blue violet, Aniline blue, Erioglaurine, Arsenazo 1, Acid blue 92, Eriochrome blue black B, Congo red, Acid blue 29, Nile blue A, Reactive blue 2, Basic red 15, D&C green No. 5, and combinations thereof.

47. (Original) The method of claim 42, wherein the indicator composition comprises at least one copper salt.

48. (Previously Presented) The method of claim 47, wherein the colorant is selected from the group of classes of colorants consisting of Methane, Monoazo, Diazo, Triazo, Diazine, Thiazine, Xanthene, Oxazine, Cyanine, and Anthraquinone colorants, and combinations thereof, and/or a colorant selected from the group consisting of Victoria green S extra, Basic blue 41, Basic red 15, Acid green AX986, and Basic red 14 colorants, and combinations thereof.

49. (Previously Presented) The method of claim 47, wherein the colorant is selected from the group consisting of Alphazurine A, Methyl violet 2B, Ethyl violet, FD/C blue 1, Brilliant blue R, Lissamine green B, Erioglaurine, Victoria pure blue BO, Acid fuchsin sodium salt, Patent blue violet, Guinea green B, Coomassie violet R 150, Mordant brown 48, Chromotrope 2B, D&C red No. 33, Bordeaux R, Acid violet 7, Acid violet 5, Plasmocorinth, Acid red 151, Acid blue 29, Acid black 24, Acid red 97, Direct red 75, Brilliant crocein MOO, Ponceau SS, Reactive black 5, Arsenazo 111, Direct blue 71, Azocarmine G, Methylene violet 3RAX, Toluidine blue O, Azure B, Methylene green, Sulforhodamine B, Rhodanine 6G, Violamine R, Nile blue A, Basic blue 3, Brilliant cresyl blue BB, Quinaldine red, Basic red 15, Alizarin violet 3R, Reactive blue 2, Victoria green S extra, Basic blue 41, Acid green AX986, Basic red 14, D&C green No. 5, Fast green FCF, and combinations thereof.

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50. (Currently Amended) The method of claim 47, wherein the colorant is selected from the group consisting of Alphazurine A, Methyl violet 2B, Ethyl violet, FD/C blue 1, Brilliant blue R, Lissamine green B, Erioglaucine, Victoria pure blue BO, Acid fuchsin sodium salt, Coomassie violet R 150, Mordant brown 48, Acid violet 5, Plasmocorinth, Acid red 151, Acid blue 29, Acid black 24, Acid red 97, Direct red 75, Arsenazo 111, Azocarmine G, Methylene violet 3RAX, Toluidine blue O, Methylene green, Rhodanine 6G, Basic blue 3, Brilliant cresyl blue BB, Quinaldine red, Basic red 15, Reactive blue 2, Victoria green S extra, Basic blue 41, Basic red 14, D&C green No. 5, and combinations thereof.

51. (Original) The method of claim 42, wherein the indicator composition comprises at least one iron salt.

52. (Previously Presented) The method of claim 51, wherein the colorant is selected from the group of classes of colorants consisting of Methane, Monoazo, Diazo, Triazo, Diazine, Thiazine, Cyanine, Xanthene, Oxazine, and Anthraquinone colorants, and combinations thereof, and/or a colorant selected from the group consisting of Victoria green S extra, Basic blue 41, Basic red 15, Acid green AX986, and Basic red 14 colorants, and combinations thereof.

53. (Previously Presented) The method of claim 51, wherein the colorant is selected from the group consisting of Patent blue violet, Alkali blue 4B, Victoria pure blue BO, Acid fuchsin sodium salt, Alphazurine A, Methyl violet 2B, Ethyl violet, FD/C blue 1, Brilliant blue R, Lissamine green B, Erioglaucine, Eriochrome black T, Eriochrome blue black B, Cibacron brilliant red 3B, Chromotrope 2B, Amaranth, D&C red No. 33, Bordeaux R, Acid violet 7, Acid violet 5, Plasmocorinth B, Acid blue 113, Acid red 151, Acid black 24, Acid red 97, Direct red 75, Brilliant crocein MOO, Ponceau SS, Reactive black 5, Arsenazo 111, Direct blue 71, Azocarmine G, Methylene violet 3RAX, Toluidine blue O, Methylene green, Sulforhodamine B,

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Rhodanine 6G, Violamine R, Nile blue A, Basic blue 3, Brilliant cresyl blue BB, Quinaldine red, Basic red 15, Alizarin violet 3R, Victoria green S extra, Basic blue 41, Acid green AX986, Basic red 14, D&C green No. 5, and combinations thereof.

54. (Previously Presented) The method of claim 51, wherein the colorant is selected from the group consisting of Victoria pure blue BO, Acid fuchsin sodium salt, Alphazurine A, Methyl violet 2B, Ethyl violet, FD/C blue 1, Brilliant blue R, Lissamine green B, Erioglaucine, Eriochrome black T, Eriochrome blue black B, Cibacron brilliant red 3B, Chromotrope 2B, D&C red No. 33, Acid violet 7, Acid violet 5, Plasmocorinth B, Acid blue 113, Acid red 151, Acid black 24, Acid red 97, Direct red 75, Brilliant crocein MOO, Ponceau SS, Reactive black 5, Arsenazo 111, Azocarmine G, Methylene violet 3RAX, Toluidine blue O, Methylene green, Sulforhodamine B, Rhodanine 6G, Violamine R, Nile blue A, Basic blue 3, Brilliant cresyl blue BB, Basic red 15, Alizarin violet 3R, Victoria green S extra, Basic blue 41, Acid green AX986, Basic red 14, D&C green No. 5, and combinations thereof.

55. (Original) The method of claim 42, wherein the indicator composition comprises a chromium salt.

56. (Original) The method of claim 55, wherein the colorant is selected from the group of classes of colorants consisting of Methane, Monoazo, Diazo, and Cyanine colorants, and combinations thereof.

57. (Original) The method of claim 55, wherein the colorant is selected from the group consisting of Ethyl violet, Eriochrome black T, Eriochrome blue black B, Congo red, Acid blue 113, Quinaldine red, and combinations thereof.

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58. (Original) The method of claim 55 wherein the colorant is selected from the group consisting of Ethyl violet, Eriochrome black T, Eriochrome blue black B, Acid blue 113, Quinaldine red, and combinations thereof.

59. – 68. (Cancelled)